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EXAMINER	
POLANSKY, GREGG	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/569,863	HOLM ET AL.	
	Examiner	Art Unit	
	GREGG POLANSKY	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,31-34,36-44 and 51-56* is/are pending in the application.

4a) Of the above claim(s) *2,12,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,13-29,31-34,36,37,40-44 and 51-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicants' Information Disclosure Statement, filed 11/10/2008, is acknowledged and has been reviewed.

2. Applicants' response, filed 11/10/2008, to the Office Action mailed 5/09/2008 is acknowledged. Applicants canceled Claims 30 and 35, amended Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51, added Claims 52-56, and presented arguments in response to the Office Action.

3. Claim 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51-56 are presently under consideration.

4. Applicants' arguments have been fully considered and are persuasive in part. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

5. It is noted that the claims have been amended to remove the recitation of "Prografs". Applicants are reminded that the text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters.

Specification

6. The incorporation of essential material in the Specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicants are **required** to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the Applicants, or a practitioner representing the Applicants, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). See Specification, page 1, line 18, EP-A-O 444 659. This objection is maintained from the previous Office Action. Applicants have failed to respond to this objection.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. **Compliance will not be held in abeyance** with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Applicants clearly consider the teachings of the references to be essential to the present invention since they have pointed to the references in their present arguments in response to the Written Description rejection to tacrolimus analogues of record (see below).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-11, 13-37, 40-44 and 51 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, Claim 42 recites the broad recitation "about 10 w/w%", and the claim also recites "preferable at the most about 7.5 w/w%".

The phrase "between about" in Claim 1, "from about" in Claims 22, and 23 and "at least about" in Claims 7, 37 and 44, renders the claims indefinite because it is unclear as to what range is covered. The claims lack clarity as to whether "between", "at least" or "from" (minimum) or "about" (broadening limitation, both higher and lower) control the metes and bounds of the phrases "between about", "from about" and "at least about".

Applicants argue the term "about" is definite.

Applicants' argument does not address the rejection at hand. The rejection is to the use of the terms "between about", "from about" and "at least about"; the rejection is not to the use of the term "about".

Regarding Claim 41, the term "including" renders the claims indefinite because it allows for the inclusion of elements not actually disclosed, thereby rendering the scope of the claims unascertainable.

Applicants argue the term "including" has been removed from the claims; however, the use of the term "including" remains in Claim 41.

Claim 42 recites a solid dosage form, which upon oral administration "releases at the most about 10 w/w%, preferably at the most about 7.5 w/w%". The claim does not recite what is being released or over what time period it is released, thereby rendering the claim indefinite.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44, 51, 53, 55, and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Claims contain subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 1 has been amended to require a pharmaceutical composition that is "free of organic solvent". Likewise, new Claim 56 is drawn to a pharmaceutical composition that is "free of organic solvent". Applicants assert that support for this new requirement "can be found at, for example, page 25, line 35 to page 26, line 1 and original claims 13, 14, 16 and 17".

The Examiner disagrees with this assertion. The Specification at page 25, line 35 to page 26, line 1 states "Apart from using the organic solvent based method, solid dispersion or solid solutions of tacrolimus and/or an analogue thereof may be obtained by dispersing and/or dissolving tacrolimus in the carrier composition used in the controlled agglomeration method. Stabilizing agents etc. may be added in order to ensure the stability of the solid dispersion/solution." Although one may infer from this disclosure that no organic solvent was used in making the solid dispersion/solution of tacrolimus, the disclosure does not exclude the presence of an organic solvent in a

composition of said tacrolimus solid dispersion/solution. For example, an organic solvent may be introduced to the composition during the process of coating a dosage form of the composition. The Specification does not explicitly or implicitly disclose a composition which is free of organic solvent.

11. Claims 1, 3-11, 13-37, 40-44 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claims recite "tacrolimus or **analogues thereof**" (emphasis added). There is insufficient written basis for analogues of tacrolimus in the Specification.

Regarding the requirement for adequate written description of chemical entities, Applicants' attention is directed to MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.,* 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Elli Liily*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.1 "Written Description" Requirement ("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by

"showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. At 1106 (emphasis added)). Moreover, although *Elli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicants have failed to provide any structural characteristics, chemical formula, name(s) or physical properties of analogues of tacrolimus, aside from a broad recitation that such are contemplated for use in the invention. As such, it is not apparent that Applicants were actually in possession of, and intended to use within the context of the present invention, any specific analogues of tacrolimus at the time the present invention was made. The skilled artisan could not "immediately envisage" the claimed compounds based on the description in the disclosure.

Applicants argue "[t]he specification provides support for what an analogue of tacrolimus encompasses. For example, two references (European Patent Publication No. 444659-A and U.S. Patent No. 6,387,918) describing tacrolimus analogues (including the various structures and chemical names) are incorporated by reference on the first page of the specification (see page 1, 11. 17-19). These references, along with the definition of "analogue" given on page 5 of the specification, provide a definite space

of what an analogue encompasses. Therefore, analogues of tacrolimus would have been immediately envisaged after reading the specification."

This argument is not persuasive. First, as discussed *supra*, the incorporation by reference of the European Patent Publication is not effective and the teachings of the reference have not been considered. Further, with regard to the incorporation of the U.S. Patent, Applicants have not distinctly pointed to any specific teaching of tacrolimus analogues in the reference. Second, the definition of analogue given on page 5 of the Specification, "the term 'analogue' means a chemical compound that is structurally similar to another", is a generic definition of analogue and does not provide any guidance to allow the skilled artisan to "immediately envisage" the claimed compounds.

12. Claims 27, 28, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a Written Description rejection.

The claims recite "cellulose derivatives", "silica acid or a derivative or salt thereof" and "phthalate derivatives". There is insufficient written basis for derivatives of cellulose, silica acid or phthalate in the Specification.

Regarding the requirement for adequate written description of chemical entities see the discussion *supra*.

Applicants have failed to provide any structural characteristics, chemical formula, name(s) or physical properties of analogues of tacrolimus, aside from a broad recitation

and exemplary agents that such are contemplated for use in the invention. As such, it is not apparent that Applicants were actually in possession of, and intended to use within the context of the present invention, any specific derivatives of cellulose, silica acid or phthalate at the time the present invention was made. The skilled artisan could not "immediately envisage" the claimed compounds based on the description in the disclosure.

Applicants argue "cellulose derivatives", "silica acid derivatives" and "phthalate derivatives" are disclosed in the Specification.

Applicants' arguments are not persuasive. The Specification merely discloses examples of said derivatives and does not disclose sufficient detailed, relevant identifying characteristics, including, functional characteristics when coupled with a known or disclosed correlation between function and structure of the derivatives.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (U.S. Patent Application Pub. No. 2003/0180352 A1).

Patel et al. teach a solid dosage formulation comprising tacrolimus, PEG-24 cholesterol ether (SOLULAN C-24), distilled monoglycerides, and deoxycholic acid, coated on nonpareil seed having a diameter of about 400 to 500 μm. See page 41, paragraph 425. The concentration of tacrolimus in the formulation is 2 % (w/w). Distilled monoglycerides are an oily hydrophobic material with a melting point >60°C. The reference teaches the formulation may also "include additional additive, excipients, and other components for the purpose of facilitating the processes involving the preparation of the composition or the pharmaceutical dosage form, as described [in the reference and] as is well-known to those skilled in the art". See page 41, paragraph 417. Patel et al. further disclose a wide variety of active ingredients (including tacrolimus) which may be dispersed in a solid carrier which comprises *inter alia* hydrophilic surfactants, including polyethylene glycol 6000 (PEG 6000). See Abstract; page 6, paragraph 76; page 9, paragraph 108 and page 43, paragraph 436. Patel et al. teach the compositions can be used for improved delivery of active ingredients. Figures 1-3 of the disclosure demonstrate improved release rates of various agents (as compared to commercial products or pure bulk drug) formulated by the methods taught by Patel et al. The reference discloses the "active agent can be solubilized, dispersed, or partially solubilized and dispersed" in an encapsulation coat. See page 4, paragraph 55. Patel et al. teach poloxamers, including poloxamer 188 among the most preferred surfactants for the disclosed formulations. See page 21, paragraph 183; page 23, paragraph 201. The hydrophilic surfactants utilized can be a single surfactant of a mixture of surfactants. See page 13, paragraph 144. With respect to claimed

concentration ranges of the surfactants (i.e., polyethylene glycols and poloxamers) in the instant methods, it is not inventive to discover the optimum or workable ranges by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(11). Patel et al. teach the formulations may include additives, including binders, fillers, flavorants, preservatives, antioxidants, bufferants, and disintegrants. See pages 27-28, paragraphs 236-260. Specific additives include, magnesium aluminum silicate, fumed silica (silicon dioxide), ethyl cellulose, cellulose acetate, cellulose nitrate, GELUCIRE 62/05, GELUCIRE 44/14, GELUCIRE 50/13, cellulose acetate phthalate (a water-miscible polymer with pH-dependent water solubility, utilized in enteric coatings). See pages 25-26, paragraph 216; page 27, paragraphs 237 and 242; page 28, paragraphs 259-260; and page 30, paragraph 280. The reference to Patel et al. further teaches a pharmaceutical composition in the form of a solid carrier wherein the solid carrier is prepared by a process without the need of introducing organic solvents. See page 2, paragraph 24 and page 45, claim 27

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the

inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Also see *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005) (holding that a prior art patent to an anhydrous form of a compound "inherently" anticipated the claimed hemihydrate form of the compound because practicing the process in the prior art to manufacture the anhydrous compound "inherently results in at least trace amounts of" the claimed hemihydrate even if the prior art did not discuss or recognize the hemihydrate).

In the instant case, absent evidence to the contrary, it would be expected that the release rates of tacrolimus from the formulation taught by Patel et al. would be the same as those recited by instant Claims 8-10 and 42-44. Additionally, one would expect, absent evidence to the contrary, that the tacrolimus formulation taught by Patel et al. would have a similar bioequivalence to the formulation of the instant methods.

The Patel et al. disclosure teaches or suggests all of the limitations of the instant claims. It would have been obvious to one of ordinary skill at the time of the invention, who was motivated to improve the release profile of formulations of tacrolimus, to utilize the methods taught by Patel et al.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicants argue Patel et al. does not disclose or suggest a solid pharmaceutical tacrolimus composition that is free of organic solvent as recited in claim 1.

The Examiner disagrees. As presented supra, Patel et al. disclose a pharmaceutical composition in the form of a solid carrier wherein the solid carrier is prepared by a process without the need of introducing organic solvents.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 6-12, 17-23, 26-32, 34-37, 63 and 64 of copending Application No. 10/513807. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite similar formulation, utilizing similar constituents, differing only by the active agent of the formulations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants have requested the rejection be held in abeyance until allowance of the '807 Application. Accordingly, the rejection is maintained and amended to include new Claims 52-56

17. Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51-56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-50 of copending Application No. 11/885992. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to similar pharmaceutical compositions of tacrolimus or tacrolimus

analogues and methods of preparation of said compositions. Application No. 11/885992 was filed simultaneously to the mailing of the previous Office Action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. Claims 1, 3-11, 13-29, 31-34, 36, 37, 40-44 and 51-56 are rejected.

19. No claims are allowed.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGG POLANSKY whose telephone number is

(571)272-9070. The examiner can normally be reached on Mon-Thur 9:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregg Polansky/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614